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08/813,323 03/10/97 BALTIMORE D 50659/JFW/JM

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EXAMINER

EYLER, Y

ART UNIT

PAPER NUMBER

1642

16

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
08/813,323

Applicant(s)
Baltimore et al.

Examiner
Yvonne Eyer

Group Art Unit
1642



☒ Responsive to communication(s) filed on Mar 30, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1 and 3-20 is/are pending in the application.

Of the above, claim(s) 5-20 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 3, and 4 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Response to Amendment

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 3-20 are pending in the application. Claims 1, 3, and 4 are under consideration.

Specification

The objection to the disclosure is withdrawn in light of the amendment thereto.

Claim Rejections Withdrawn:

1. All rejections of Claim 2 are rejected withdrawn in light of the cancellation of the claim.
2. The rejection of Claims 1, 3, and 4 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in light of the amendments to the claims.
3. The rejection of Claims 1, 3, and 4 under 35 U.S.C. 102(b) as being anticipated by Cheng et al. (Science 267:11494-1498, March 10, 1995-IDS) is withdrawn.

Claim Rejections Maintained and New Grounds of Rejection:

4. The rejection of Claims 1, 3 and 4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

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The basis of rejection that a truncated protein “comprising” is confusing has been rendered moot by the amendment to the claims.

The referral to sequence of Figure 1 somewhat clarifies the basis of rejection but is improper. 37 CFR 1.821 states that where the description or claims of a patent application discuss a sequence that is set forth, reference must be made to the sequence by use of the sequence identifier, preceded by SEQ ID NO: in the text of the description or claims. Also, upon further consideration, reference to human or mouse CRAF1 is vague and indefinite because the reference is to an arbitrary name.

With regard to the metes and bounds of “CD40-mediated cell activation” applicant argues that one of skill in the art would know how to determine cell activation and would know what the metes and bounds of CD40-mediated cell activation were. Applicant refers to Exhibit 1, Potocnik et al., page 24 of the instant specification, and Hu et al. in support. Applicant's arguments and the cited references do not clarify the metes and bounds of CD40-mediated cell activation. Potocnik et al. do not teach regarding the metes and bounds of “CD40-mediated cell activation.” Potocnik et al. teach that CD40 expression is upregulated on T cells from RA patients. Whether those T cells are activated and if such activation is mediated by CD40 is not addressed, nor are any other cells addressed. Similar, page 24 of the specification discloses regarding the ability of truncated CRAF1 to inhibit CD40-mediated triggering of Ramos cells to upregulate CD23 but does not disclose regarding CD40-mediated cell activation. Finally, Hu et al. teach that CD40 activation is critical for B-cell proliferation, immunoglobulin class switching, and rescue of germinal center B

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cells but does not address the metes and bounds of CD40 cell-mediated activation. Measurable, defined parameters that result after CD40 activation are not equivalent to and do not teach regarding the metes and bounds of "CD40-mediated cell activation." As indicated in the previous office action, the specification contemplates that "activation" may include any and all intracellular signaling, immune responses, allergic responses, and apoptosis (pages 14-18), the metes and bounds of which are not clearly defined by a few specific examples. "CD40 mediated cell activation" is vague and indefinite because it is not clear what measurable properties of "activation" correlate with CD40 mediated cell "activation," nor is it clear when a cell is determined to be "activated."

5. The rejection of Claims 1, 3 and 4 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained with regard to the determination of variants which inhibit CD40-mediated cell activation. All other bases of rejection are withdrawn in light of the amendments to the claims.

With regard to cell activation, applicant argues as above that one of skill would know how to determine CD40 mediated cell activation and its inhibition commensurate in scope with the claimed invention. Applicant refers again to Potocnik et al. and to the working example of CD23 upregulation. These arguments have been considered but have not been found to be persuasive because they are not commensurate in scope with the claimed invention. As discussed supra, "activation" may include (but is not limited to) any and all intracellular signaling, immune

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responses, allergic responses, and apoptosis (pages 14-18). Working examples of measurable, defined parameters that result after CD40 activation of specific cells are not equivalent to and do not teach regarding the full scope of "CD40-mediated cell activation." This is not rectified by the teachings of Potocnik et al. which do not address determination of CD40-mediated cell activation.

6. Claims 1, 3, and 4 are newly rejected under 35 U.S.C. 102(a) as being anticipated Cheng et al. (Science 267:11494-1498, March 10, 1995-IDS).

Cheng et al. teach that truncated CRAF1, clone C26, identical to the instant product, inhibits CD40-mediated up-regulation of CD23.

Applicants intention to file a declaration under 1.132 that Cheng et al. is not a publication by others is noted, however, until such time as this is established, Cheng et al. remains prior art.

7. The rejection of Claims 1, 3, and 4 under 35 U.S.C. 102(b) as being anticipated by Sato et al. (Febs Lett. 358:113-118, Jan. 23, 1995) or Hu et al. (J. Biol.Chem. 269:30069-30072, Dec. 1994-IDS) is maintained.

Applicant argues that Sato et al. does not teach the truncated protein as claimed because CAP1 is a different length than CRAF1 and there are numerous amino acid differences between CAP1 and CRAF1. Applicant concludes that since the proteins are different, so then are the truncated versions. This argument has been considered but is not found to be persuasive. Since the claims are not drawn to a full length protein, the length of the protein taught by Sato et al. is irrelevant so long as Sato et al. teach a peptide that meets the instant claim requirements. Also, the instantly claimed truncated proteins encompasses conservative variants and thus the sequence

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of the art peptide need not be completely identical. Never-the-less, sequence comparison between CRAF1 and Sato et al's CAP1 reveal two amino acid mismatches at positions 338 and 373 which are not included in the truncated protein taught by Sato et al. which begins at residue 384, after the mismatches. Thus, the truncated protein of Sato et al., starting at CAP1 residue 384 and ending at CAP1 residue 540, including the TRAF domain and sufficient for binding CD40, is identical to the instantly claimed truncated proteins.

Applicant further argues that Hu et al. does not teach a truncated version of CD40bp but only teaches the full length protein and truncated TRAF2. This is not found to be persuasive. Hu et al. state on page 30072, column 2, lines 2-5: "...one class of interacting CD40bp cDNAs identified in the two-hybrid screen encoded only the C-terminal half of CD40bp (beginning at Phe 297, which deletes the RING finger and truncates the coiled-coil segment)."

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yvonne Eyler, Ph.D. whose telephone number is (703) 308-6564. The examiner can normally be reached on Monday through Friday from 830am to 630pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-2731. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [paula.hutzell@uspto.gov].


All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Yvonne Eyler
Patent Examiner

Yvonne Eyler, Ph.D.
Patent examiner
June 3, 1999